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6 IN THE UNITED STATES DISTRICT COURT
7 FOR THE DISTRICT OF ARIZONA
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9 United States of America, ex rel. Patricia)
10 Haight and In Defense of Animals,

11 Plaintiffs,

12 vs.

13 Catholic Healthcare West, et al.,

14 Defendants.
15

No. CV-01-2253-PHX-FJM

ORDER

16
17 The court has before it defendants' motion for summary judgment (doc. 182),
18 plaintiffs' response (doc. 194), and defendants' reply (doc. 202); and plaintiffs' motion for
19 partial summary judgment (doc. 185), defendants' response (doc. 198), and plaintiffs' reply
20 (doc. 203).

21 Defendants also filed two motions to strike, one to strike expert opinions (doc. 200),
22 the other to strike plaintiffs' consolidated statement of undisputed facts (doc. 205). Both of
23 these motions are improper under Rule 12(f), Fed. R. Civ. P., which applies only to
24 "pleadings" under Rule 7(a), Fed. R. Civ. P., and not to motions and other papers under Rule
25 7(b), Fed. R. Civ. P. Therefore, both motions to strike are denied (docs. 200, 205).
26 Nevertheless, plaintiffs' document entitled "Consolidated Reply Statement of Undisputed
27 Material Facts" (doc. 204) is not authorized by the federal or local rules, and accordingly we
28 do not consider it.

1 Defendants also submitted a Rule 12(b)(1) motion to dismiss the animal welfare
2 assurance claim (doc. 181). The claim is now moot based on the plaintiffs' concession that
3 they "do not claim the Animal Welfare Assurance number itself is a false statement."
4 Plaintiffs' Response at 10 (doc. 194). Accordingly, this motion is denied on grounds of
5 mootness (doc. 181).

6 I

7 Plaintiffs brought this action under the *qui tam* provisions of the False Claims Act, 31
8 U.S.C. §§ 3729-3733 ("FCA"), alleging that defendants made false statements in connection
9 with a research grant application to the National Institutes of Health ("NIH"), which resulted
10 in a grant award to defendants of over \$700,000. We originally dismissed the action for lack
11 of subject matter jurisdiction, concluding that plaintiffs' claims were based on publicly
12 disclosed information, and that plaintiffs were not the original source of the information.
13 Specifically, we found that the NIH grant application, which was obtained pursuant to a
14 Freedom of Information Act ("FOIA") request, was an "administrative report" that was
15 barred by the public disclosure provision of the FCA. The Ninth Circuit reversed and
16 remanded, holding that a response to an FOIA request is not necessarily a "report" or
17 "investigation" by the government for purpose of the public disclosure bar. United States
18 ex rel. Haight v. Catholic Healthcare West, 445 F.3d 1147, 1156 (9th Cir. 2006). Instead,
19 whether the jurisdictional bar applies is "determined by reference to the nature of that
20 document itself." Id. The court concluded that the NIH grant application obtained in
21 response to the FOIA request does not qualify as a publicly disclosed document, and
22 therefore plaintiffs' action is not barred. The case is before us once again.

23 II

24 In October 1997, defendant Michael Berens, Ph.D., as principal investigator on behalf
25 of defendants' research institutions, submitted a grant application to the NIH, entitled
26 "Allogenic Glioma in Immune Competent Dogs" ("the October 1997 grant application").
27 Defendants sought federal funding in connection with Dr. Berens' project to develop a canine
28 model to study glioma, a form of human brain cancer. In his research, Dr. Berens attempted

1 to develop a method for implanting gliomas in the brains of beagles, by first injecting
2 cancerous cells into the flanks of prenatal pups, and later transplanting resulting
3 subcutaneous tumors from the live born pups into the brains of the same dogs. The theory
4 was that by implanting the cancer cells from a different genetic source (“allogenic”) at the
5 right time of gestation, the developing immune system in the fetal pup will recognize the
6 tissue as its own, and will therefore allow implanted cancer cells to thrive without the use of
7 immuno-suppressants that would otherwise compromise the immune systems of the study
8 dogs.

9 Plaintiff In Defense of Animals is a national animal advocacy organization devoted
10 to protecting the rights of animals. Plaintiff Patricia Haight is the Southwest Regional
11 Director of In Defense of Animals. Plaintiffs claim that defendants violated the False Claims
12 Act, 31 U.S.C. § 3729(a), by knowingly making false statements in their October 1997 grant
13 application in order to improperly obtain NIH funds. The parties have now filed cross-
14 motions for summary judgment.

15 III

16 The *qui tam* provisions of the False Claims Act permit private individuals to sue, on
17 behalf of the United States, persons or entities who “knowingly make[] . . . a false record or
18 statement to get a false or fraudulent claim paid or approved by the Government.” *Id.* A
19 person “knowingly” submits a false claim if, with respect to information in the claim, the
20 person “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the
21 truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of
22 the information, and no proof of specific intent to defraud is required.” *Id.* at § 3729(b).

23 At a minimum, falsity under the FCA requires proof of an objective falsehood. An
24 untrue statement is not sufficient by itself to warrant liability under the FCA; the Act
25 “requires a showing of knowing fraud.” Hagood v. Sonoma County Water Agency, 81 F.3d
26 1465, 1478 (9th Cir. 1996). “Expressions of opinion, scientific judgment, or statements as
27 to conclusions about which reasonable minds may differ cannot be false.” United States ex
28 rel. Roby v. Boeing Co., 100 F. Supp. 2d 619, 625 (S.D. Ohio) (citing Wang ex rel. United

1 States v. FMC Corp., 975 F.2d 1412, 1420-21 (9th Cir. 1992)). Falsity under the Act “does
 2 not mean ‘scientifically untrue’; it means ‘a lie.’ ” Wang, 975 F.2d at 1421. The Act is
 3 concerned about “ferreting out ‘wrongdoing,’ not scientific errors.” Id.

4 IV

5 Plaintiffs claim that defendants knowingly made false statements in the October 1997
 6 grant application in order to obtain NIH funds. Specifically, plaintiffs assert that Dr. Berens
 7 (1) inflated the success rate in his preliminary studies; (2) propagated a falsehood by
 8 presenting unattainable “specific aims”; (3) omitted material information on experimental
 9 failures and expected outcomes; and (4) misrepresented the nature of Dr. Geoffrey
 10 Pilkington’s collaboration in the project. We now examine the specific alleged false
 11 statements.

12 A. Inflated Success Rate in Preliminary Studies

13 Plaintiffs contend that after repeated unsuccessful attempts to win federal funding for
 14 his project, Dr. Berens substantially revised his October 1997 grant application by deleting
 15 prior statements of potential difficulties and falsely inflating the claimed success rate of his
 16 preliminary studies. Plaintiffs assert that defendants made three false statements regarding
 17 the results of preliminary studies.

18 1.

19 In February 1997, Dr. Berens submitted a grant application in which he stated that
 20 “evidence of immune tolerance to the allogenic glioma cells is manifest by the presence of
 21 subcutaneous tumors in up to 60% of the pups (in one case).” Plaintiffs’ Exhibit 11B at 37.
 22 Dr. Berens revised this statement in his October 1997 grant application to provide that
 23 “evidence of immune tolerance to the allogenic glioma cells is manifest by the presence of
 24 subcutaneous **tumors in up to 80% of the pups.**” Grant Application at 38 (emphasis in
 25 original). Dr. Berens similarly stated that “4 of 5 pups in one litter developed tumors.” Id.
 26 at 41. Plaintiffs claim that without any additional data to support the upgrade, Dr. Berens
 27 fraudulently increased the success rate from 60% to 80% in order to ensure the approval of
 28 his grant application.

1 Defendants counter that the research records confirm that four out of five pups (80%)
2 born to dam Yental (pups identified as Y2, Y3, Y4, and Y5) developed tumors. DSOF ¶¶
3 24, 31-34. Defendants claim that before submission of the February 1997 grant application,
4 three of five pups (60%) from Yental's litter, Y2, Y4, and Y5, were observed to have tumors.
5 Y3's tumor was first observed in May 1997, after submission of the February 1997 grant
6 application. DSOF ¶ 33. Defendants argue that this new information supports the claimed
7 increase in the success rate from 60% to 80%.

8 Plaintiffs also challenge Dr. Berens' method of identifying subcutaneous tumors,
9 namely palpation of subcutaneous masses at the site of the injection. Plaintiffs reject this
10 method, instead interpreting Dr. Berens' research protocol as requiring histologic
11 confirmation of "subcutaneous *glioma* tumors." Plaintiffs' Response at 3 (emphasis added).
12 Plaintiffs' expert, Dr. Lawrence Hansen opined that "it is essential that suspected
13 subcutaneous tumors are properly verified as glial" and that such tumors must be identified
14 by a "histologic evaluation." Id.

15 The statements at issue in the October 1997 grant application specifically reported that
16 "subcutaneous tumors" were found in "up to 80% of the pups," not "glioma tumors." There
17 is no evidence to suggest that histologic confirmation is required to observe a "subcutaneous
18 tumor." In fact, defendants' expert opined that "[m]ost of the research doesn't use histologic
19 confirmation of tumors," and that palpation is a specific protocol accepted by the NIH.
20 DSOF ¶ 36. Plaintiffs' argument that Dr. Berens' research protocol required identification
21 of subcutaneous glioma tumors amounts to criticism of the rationale underlying Dr. Berens'
22 research protocol. But the False Claims Act protects against fraud. It is not a vehicle to
23 vindicate contrary views.

24 Plaintiffs also argue that regardless of the method used to identify tumors, the
25 evidence does not support the claim that four of Yental's five pups developed subcutaneous
26 tumors. Plaintiffs' Response at 5. They claim that Y2's tumor does not count because it
27 resorbed; Y3's tumor does not count because it did not develop until a year after birth; Y4's
28 tumor does not count because the slide confirming the 1996 histology of the tumor could not

1 be found; and Y5's tumor does not count because it was found during an autopsy. Plaintiffs
 2 do not deny that tumors existed in these pups, but contend that the quality of the tumors was
 3 inadequate to reasonably support the statement that "4 of 5 pups in one litter developed
 4 tumors." As noted, expressions of scientific opinion or judgment about which reasonable
 5 minds may differ cannot be false. See Wang, 975 F.2d at 1420-21. Whether the quality of
 6 a particular tumor is sufficient to classify it as a "subcutaneous tumor" involves a scientific
 7 judgment or opinion and cannot serve as the basis for an FCA claim. See United States ex
 8 rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999) (citing Wang, 975
 9 F.2d at 1420-21) ("errors based simply on . . . flawed reasoning are not false under the
 10 FCA").

11 2.

12 Plaintiffs next claim that the defendants falsely stated in their October 1997 grant
 13 application that, "[m]ost recently, cells from one of the clones was used to induce immune
 14 tolerance in fetal dogs in four separate litters," Grant Application at 35, and that "[s]uccessful
 15 allo-tolerant pups from four separate litters have been achieved." Grant Application at 41.
 16 Defendants contend that these statements are true and that research records confirm that
 17 before submission of the October 1997 grant application, dogs from four separate litters
 18 (from dams Yental, Tess, Winnie, and Maggie) had histologically confirmed subcutaneous
 19 gliomas after having been fetally implanted with cancer cells. DSOF ¶¶ 21-27.

20 Plaintiffs' expert, Dr. Hansen, confirmed that evidence showed subcutaneous gliomas
 21 in pups from four separate litters. DSOF, exhibit 10 at 55-56; DSOF ¶¶ 21-27. Now
 22 acknowledging that the evidence supports the existence of glioma tumors, Plaintiff's
 23 Response at 4, plaintiffs instead argue that the phrase "most recently" does not accurately
 24 describe tests conducted in September 1993, June 1994, and May 1995. We reject this
 25 argument. A vague, undefined phrase such as "most recently" is not an objective statement
 26 of fact upon which a false claims action can be based. See Morris v. Princess Cruises, Inc.,
 27 236 F.3d 1061, 1067-68 (9th Cir. 2001) (holding that statements lacking "meaningful
 28

specificity” cannot support a fraud claim). These statements are not actionable under the False Claims Act.

3.

Plaintiffs also challenge defendants’ statement that “[i]n the past two years, one in four litters yielded at least one pup with a tumor.” Grant Application at 48. Defendants assert that from October 1995 through October 1997, the two years before submission of the October 1997 grant application, eighteen different dams underwent fetal implant surgery. Of those eighteen dams, five gave birth to at least one dog that developed a subcutaneous tumor. DSOF ¶¶ 40-58. Therefore, according to defendants, the challenged statement is true.

While plaintiffs acknowledge that “lumps,” “growths,” or “tumors” were identified in these five litters, they argue that a particular growth was insufficient to support the statement that “one in four litters yielded at least one pup with a tumor.” For example, plaintiffs challenge tumors that were discovered during autopsies, arguing that “if the pup cannot survive . . . it cannot be used as a study dog.” Plaintiffs’ Response to DSOF ¶ 54 (doc. 195). This argument, however, does not refute the statement that a tumor was observed.

Plaintiffs also challenge defendants’ identification of two pups (Z2 and Z3) born to dam Sassy as having developed lumps or growths shortly after birth. DSOF ¶ 50. Although plaintiffs acknowledge that lumps or growths were observed initially, because the treatment notes stop referencing the growths, plaintiffs assert that an assumption must be made that these growths were not glioma tumors. Again, plaintiffs attempt to rewrite the grant application as expressing that one in four litters yielded at least one pup with a *glioma* tumor. This argument does not accurately characterize the statement at issue. Moreover, whether a growth that subsequently resorbs is appropriately considered a “tumor” for purposes of assessing the success rate of the preliminary studies is a matter of scientific judgment about which reasonable minds may differ, and thus cannot be false for purposes of the FCA.

B. Unrealistic “Specific Aims”

1 Plaintiffs assert that defendants presented a false and fraudulent “factorial design” in
2 their October 1997 grant application, by projecting that they would create approximately 78
3 cranial tumors in 108 pups following surgeries in 18 dogs over three years. See Grant
4 Application at 54. Plaintiffs argue that the falsity of this statement is evidenced by the fact
5 that in the February 1997 grant application, Dr. Berens proposed to create only 20 study dogs
6 with cranial tumors—a “miraculous four-fold increase” over the October 1997 application.¹
7 They contend that Dr. Berens’ “factorial design” is unrealistic and unattainable given that
8 defendants had only produced 2 dogs with cranial glioma implants after 37 surgeries over 7
9 years.

10 Defendants counter that the statement at issue is not a “factorial design” as described
11 by plaintiffs. Instead, it is expressly identified as a “specific aim,” Grant Application at 54,
12 which, according to the NIH, is a “broad, long-term objective” for the research. DSOF ¶ 82.
13 According to defendants, the challenged statement is an outcome which they aspired to
14 achieve, not one they predicted they would achieve.

15 The grant application clearly identifies Dr. Berens’ statement as a “specific aim,” not
16 a “projection.” The statement of defendants’ broad, long-term goals following completion
17 of his project is not objectively verifiable, and therefore cannot form the basis of an FCA
18 claim. See Doe v. Howe Military Sch., 227 F.3d 981, 991 (7th Cir. 2000) (holding that
19 school’s stated “goals and objectives” are not the type of representations that would support
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26 ¹We note, however, that in language virtually identical to the February application,
27 the October 1997 application also provides that “[t]en dogs . . . will be followed for response
28 to surgery and radiation. Ten dogs will be evaluated for response to surgery, radiation and
chemotherapy.” Grant Application at 52.

a fraud claim).² Errors based simply on faulty calculations or flawed reasoning are not false under the FCA. See Wang, 975 F.2d at 1420-21.

C. Omission of Material Information

Plaintiffs next assert that defendants violated the FCA by removing statements in the February 1997 grant application that indicated persistent experimental failures and low success rates. For example, plaintiffs claim that Dr. Berens deleted from the February 1997 grant application the statement that “[t]here is a possibility that allogenic tolerance is an infrequent event, and that despite the proposed experiments, only a low success rate will be achieved.” Plaintiffs’ Exhibit 11B at 44. Moreover, plaintiffs claim that defendants failed to report that they had only a 6% success rate for inducing allogenic tolerance to subcutaneous tumors and a 1.6% success rate for cranial implants.

The False Claims Act does not impose liability for omissions unless the defendant has an obligation to disclose the omitted information. United States ex rel. Berge v. Bd. of Trustees, 104 F.3d 1453, 1461 (4th Cir. 1997). Plaintiffs fail to show how defendants were required to disclose the omitted statements. Their absence did not render the statements that were made false or misleading. In fact, defendants’ October 1997 grant application included statements of limited experimental success. For example, the October 1997 application provided that “[a]s disclosed in the prior application ‘ . . . the percentage of tumor takes . . . was ‘very low,’ ” and the purpose of the grant was “the need to improve the success rate of the procedure.” Grant Application at 28 (omissions in original). The application further acknowledged that “[o]ther litters so implanted have also failed to show even one tumor. We are brought to the recognition that the [major histocompatibility complex] may serve as an

²Plaintiffs also challenge defendants’ statement in the October 1997 grant application that “we have also achieved the technical and surgical skills necessary for realizing the desired outcome.” Grant Application at 41. Plaintiffs construe the phrase “desired outcome” as equivalent to defendants’ “specific aim” to create 78 cranial tumors. Plaintiffs do not challenge defendants’ surgical or technical skills, but only whether the “desired outcome” can be achieved. We have already concluded that defendants’ specific aim is not an objectively verifiable fact upon which a false claims action can be based.

immunological boundary through which only selected MHC genotypes could induce tolerance.” Id. at 41. Defendants’ inclusion of these statements of limited success in the October 1997 grant application significantly undermines plaintiffs’ argument that defendants knowingly defrauded the NIH by the omission of material information. Therefore, the omission of the statements at issue cannot form the basis of a false claim.

D. False Statement Regarding Dr. Pilkington’s Role

Finally, plaintiffs claim that defendants falsely stated that Dr. Geoffrey Pilkington would provide control dogs for the study. Plaintiffs’ Response at 10. In their October 1997 grant application, defendants state that they will acquire canine glioma cell lines from spontaneous tumors in control dogs, either identified from a local veterinary practice or “acquired through collaboration with Dr. Pilkington.” Grant Application at 43. Plaintiffs narrowly interpret this statement as providing that Dr. Pilkington will supply control dogs, but in fact he had not agreed to do so. In any event, Dr. Pilkington did agree to collaborate on defendants’ canine glioma project by supplying “early passage canine glioma cell cultures for analysis.” Grant Application at 70 (letter from Dr. Pilkington to Dr. Berens). Plaintiffs’ narrow construction of defendants’ statement will not serve as the basis for a false claim. They have presented no evidence to establish that the challenged statement was false.

V

We conclude that plaintiffs have failed to produce sufficient evidence from which a reasonable jury could find that the challenged statements in the October 1997 grant application were objectively false and therefore actionable under the False Claims Act. See Hagood, 81 F.3d at 1477-78; Wang, 975 F.2d at 1420-21.

Therefore, **IT IS ORDERED GRANTING** defendants’ motion for summary judgment (doc. 182) and **DENYING** plaintiffs’ motion for partial summary judgment (doc. 185).

IT IS FURTHER ORDERED DENYING defendants’ motion to strike expert opinions (doc. 200), and **DENYING** defendants’ motion to strike consolidated reply statement of undisputed material facts (doc. 205).

IT IS FURTHER ORDERED DENYING defendants' Rule 12(b)(1) motion to dismiss the animal welfare assurance claim as moot (doc. 181).

The clerk shall enter final judgment.

DATED this 14th day of August, 2007.

Frederick J. Martone
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United States District Judge